



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Braftovi (encorafenib)

Policy Number: 5.01.668
Origination: 12/2018

Last Review: 12/2018
Next Review: 12/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for **Braftovi (encorafenib)** when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Braftovi (encorafenib) may be considered **medically necessary** when all of the following criteria are met:

FDA-Approved Indications

1. **Melanoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) The patient has unresectable, advanced, or metastatic melanoma; AND
 - B) The patient has melanoma with a BRAF V600 mutation.

NCCN guidelines for melanoma (updated prior to approval of Braftovi + Mektovi) recommend other BRAF + MEK inhibitor combinations (e.g., Zelboraf + Cotellic, Tafinlar + Mekinist) for first-line and subsequent treatment of melanoma with a V600 activating mutation.³ While combination therapy with a BRAF/MEK inhibitor is preferred, NCCN notes that if contraindicated, monotherapy with a BRAF inhibitor (Tafinlar or Zelboraf) are recommended options.

When Policy Topic is not covered

Braftovi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions and may be considered **investigational**. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Considerations

Braftovi (encorafenib) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

Description of Procedure or Service

Braftovi, a BRAF inhibitor, is indicated in combination with Mektovi[®] (binimetinib tablets), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.¹ It is a limitation of use that Braftovi is not indicated for wild-type melanoma.

Disease Overview

Mutations in the *BRAF* gene are common in several types of cancer.² The BRAF protein is normally switched on and off in response to signals that control cell growth and development; however, mutations cause the BRAF protein to be continuously active. This over activity may contribute to the growth of cancers by allowing abnormal cells to grow and divide uncontrollably. The V600E mutation is the most common *BRAF* gene mutation identified in cancers, particularly in melanoma.

Rationale

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Braftovi (encorafenib) while maintaining optimal therapeutic outcomes.

References

1. Braftovi[™] capsules [prescribing information]. Boulder, CO: Array BioPharma; June 2018.
2. Genetic Home Reference. BRAF gene. National Institutes of Health, US Department of Health & Human Service Web Site. Reviewed October 2017. Accessed on May 16, 2018. Available at: <https://ghr.nlm.nih.gov/gene/BRAF>.
3. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 2.2018 – January 19, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 16, 2018.

Billing Coding/Physician Documentation Information

NA Braftovi is a pharmacy benefit

Additional Policy Key Words

N/A

Policy Implementation/Update Information

12/2018 New policy titled Braftovi (encorafenib)

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.